Rule 8. Radiation Safety Requirements for Analytical X-Ray Equipment

410 IAC 5-8-1 Scope of rule

Sec. 1. 410 IAC 5-8 provides special requirements for analytical x-ray equipment. The requirements of 410 IAC 5-8 are in addition to, and not in substitution for, applicable requirements in other parts of 410 IAC 5.

410 IAC 5-8-2 Definitions

Sec. 2. As used in 410 IAC 5-8, the following definitions apply:

"Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

"Fail-safe characteristics" mean a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Local components" mean part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data-recording procedures which are related to radiation safety.

"Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

410 IAC 5-8-3 Equipment requirements

Sec. 3. (a) Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant (or licensee) may apply to the board for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used; and

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Warning Devices.

(1) Open-beam configurations shall be provided with a readily discernible indication of:

(i) X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(ii) Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(2) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after June 25, 1978, warning devices shall have fail-safe characteristics.

(c) Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(d) Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) "CAUTION HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray source housing; and

(2) "CAUTION RADIATION THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or

(3) "CAUTION RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing in accordance with 410 IAC 5-4-11 if the radiation source is a radionuclide.

(e) Shutters. On open-beam configurations installed after June 25, 1978, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) Warning Lights. An easily visible warning light labeled with the words "X-RAY, ON," or words having a similar intent,

shall be located:

(1) Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or

(2) In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.

(3) On equipment installed after June 25, 1978, warning lights shall have fail-safe characteristics.

(g) Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:

(1) Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

(2) Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 millirems in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.

(3) If radioactive sources are used, corresponding dose limits shall not exceed 2 mrem per hour.

(h) Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour.

410 IAC 5-8-4 Area requirements; surveys; posting

Sec. 4. (a) Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 410 IAC 5-4-6. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

(b) Surveys

(1) Radiation surveys, as required by 410 IAC 5-4-9, of all analytical x-ray systems sufficient to show compliance with paragraph 410 IAC 5-8-4(a) shall be performed:

(i) Upon installation of the equipment, and at least once every 12 months thereafter;

(ii) Following any change in the initial arrangement, number or type of local components in the system;

(iii) Following any maintenance requiring the disassembly or removal of a local component in the system;

(iv) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

(v) Any time a visual inspection of the local components in the system reveals an abnormal condition; and

(vi) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 410 IAC 5-4-2.

(2) Radiation survey measurements shall not be required if a registrant (or licensee) can demonstrate compliance to the satisfaction of the board with 410 IAC 5-8-4 in some other manner.

(c) Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION X-RAY EQUIPMENT," or words having a similar intent in accordance with 410 IAC 5-4-11.

410 IAC 5-8-5 Operation requirements

Sec. 5. (a) Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.

(b) Bypassing. No person shall bypass a safety device unless such person has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

(c) Repair or Modification of X-Ray Tube Systems. Except as specified in 410 IAC 5-8-5(b), no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

(d) Radioactive Source Replacement, Testing or Repair. Radioactive source housings shall be opened for source replacement, leak testing or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state.

410 IAC 5-8-6 Personnel requirements; instruction; monitoring

Sec. 6. (a) Instruction. No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment;

(2) Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(3) Proper operating procedures for the equipment;

(4) Recognition of symptoms of an acute localized exposure; and

(5) Proper procedures for reporting an actual or suspected exposure.

(b) Personnel Monitoring.

(1) Finger or wrist dosimetric devices shall be provided to and shall be used by:

(i) Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

(ii) Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with 410 IAC 5-4-2 unless evaluated by a qualified radiation health physicist.